

STATEMENT BY

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**BEFORE
THE SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS AND
INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES**

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Mr. Chairman and members of the Committee, I appreciate the opportunity to appear before you today to discuss implementation of Public Law 105-277, the "Persian Gulf War Veterans Act" of 1998. I will also review VA's statutory obligations under section 101 of Public Law 105-368, the "Veterans Programs Enhancement Act of 1998", and will provide a status of the studies and reports on Gulf War Health conducted by the National Academy of Sciences' (NAS) Institute of Medicine (IOM).

Mr. Chairman, you expressed interest in hearing more about VA's compliance with the statutory mandate to assess the extent and weight of data from animal studies in determinations of presumptive causality of disease, not just the plausibility of a biological mechanism. While this will be discussed later in my testimony, I want to assure you that both VA and NAS carefully consider all relevant peer-reviewed animal studies, and we believe we are fully compliant with the relevant statutes.

VA's Statutory Obligations

In addition to VA's implementation of the "Persian Gulf War Veterans Act of 1998" (Gulf War Veterans Act), VA is also charged with simultaneously implementing the provision of section 101 of the "Veterans Programs Enhancement Act of 1998" (Programs Enhancement Act), which establishes an overlapping framework for addressing issues relating to the health status of Gulf War veterans. Thus, our

implementation of the former statute must take into account our responsibilities under the latter.

Although similar in purpose, there are several instances in which these statutes take seemingly different approaches to the study of health risks associated with service in the Gulf War and to provisions of compensation to veterans who may have incurred disability as a result of Gulf War service. In addition, the Gulf War Veterans Act contains a provision (section 1604) purporting to nullify "section 101 of the Veterans Programs Enhancement Act of 1998, or any similar provision of law enacted during the second session of the 105th Congress requiring an agreement with the National Academy of Sciences (NAS) regarding an evaluation of health consequences of service in Southwest Asia during the Persian Gulf War."

Section 101 of the Programs Enhancement Act requires VA to enter into a contract with NAS to conduct a review and evaluation of available scientific and medical information on the health status of Gulf War veterans and the health consequences of exposures to risk factors during service in the Gulf War, including identification of risk factors and the illnesses associated with such factors, as well as the illnesses that are manifest in such members to a higher degree than in comparison groups. The statute requires NAS to determine—to the extent that available scientific evidence permits—whether, for each illness identified, there is scientific evidence of an association with Gulf War service or exposure during Gulf War service to one or more risk factors. NAS is required to perform subsequent reviews of available evidence and data and to periodically report to VA and the Committees on Veterans' Affairs on its activities.

VA, in turn, is required to review each report from NAS and, based on that review, submit to the Committees on Veterans' Affairs a report on the available scientific and medical information regarding the health consequences of Gulf War service and of exposures to risk factors during service in the Gulf War. VA is required to include its recommendations as to whether there is sufficient evidence to warrant a presumption of service connection for the occurrence of a specified condition in Gulf War veterans.

While the Gulf War Veterans Act also includes requirements for VA to seek to enter into an agreement with NAS for the review of available scientific information regarding the health of Gulf War veterans and for preparation of biennial reports by NAS, there is a major distinction between the two statutes as to actions VA must take following receipt of a report from NAS. In particular, the Gulf War Veterans Act requires VA to determine, based on the NAS report, whether particular illnesses warrant a presumption of service connection and, if so, to promulgate regulations establishing a presumption of service connection for each such illness. This contrasts with the Programs Enhancement Act requirement that VA report to Congress any recommendations regarding the establishment of a presumption of service connection for any illness. In addition, the two acts differ in several respects concerning study details and the timing and submission of reports.

In view of the differences between the two statutes and the purported nullification provision in the Gulf War Veterans Act, on December 8, 1998, VA's General Counsel asked the Department of Justice, Office of Legal Counsel (OLC), for an opinion regarding VA's implementation of the two statutes.

On March 12, 1999, OLC responded that "(1) section 1604 of the [Gulf War Veterans Act] is constitutionally invalid and ineffective insofar as it purports to nullify certain described legislation (including section 101 of the [Programs Enhancement Act]) that might be enacted in the future; (2) under governing principles of statutory interpretation, every effort must be made to reconcile the provisions of two statutes enacted under the circumstances presented here before resorting to rules of construction for giving one primacy over the other; and (3) the respective provisions of the two laws . . . although redundant and burdensome in some respects if both laws are given effect, are not inherently conflicting or mutually exclusive, and therefore the provisions of both laws must be treated as valid and effective."

OLC determined that since the Program Enhancement Act was passed by Congress and signed into law by the President after the Gulf War Veterans Act, the Programs Enhancement Act constitutes the later enacted of the two statutes. Next, OLC determined that section 1604 of the Gulf War Veterans Act cannot constitutionally nullify the subsequent enactment of section 101 of the Programs Enhancement Act.

With respect to the areas of difference between the two statutes, OLC found the most significant variation to be the action required by VA after receiving a report from NAS. OLC determined that the two provisions are not mutually exclusive and that compliance with both of these provisions would not appear to be inordinately burdensome; therefore, VA must attempt to comply in good faith with both provisions. Consequently, VA must not only make an administrative determination with respect to creation of presumptions of service connection for particular diseases, but must also submit recommendations to Congress concerning the issue. In addition, OLC advised that compliance with both provisions will require VA to contract with NAS to address all study elements in both of the two provisions and to adhere to the earlier of any time-specific reporting requirements. In accordance with the opinion of OLC, VA has sought to give effect to both statutes in reviewing each of the reports of NAS.

The National Academy of Sciences' Institute of Medicine

The Institute of Medicine, within the National Academy of Sciences, was created and congressionally chartered more than a century ago to advise the Federal Government on scientific and technological matters. Congress has long recognized the unique scientific advisory contribution provided by IOM, and IOM conducts many studies that are statutorily required. IOM is the organization within NAS that conducts the studies required by both the Gulf War Veterans Act and the Programs Enhancement Act.

Because of IOM's independent status, VA has extensive experience relying upon the Institute for scientific and medical advice on a wide range of veterans' health issues, including health effects associated with (1) service in the Gulf War; (2) exposure to

Agent Orange during the Vietnam War; (3) exposure to mustard and Lewisite chemical warfare agents; and (4) participation in DoD's Project 112/SHAD. Of note, since 1991, IOM has completed eighteen independent reviews of the scientific and medical literature on Gulf War veterans' health (see attachment).

"Gulf War and Health" Reports Issued by the National Academy of Sciences

As I described earlier, Congress required VA to contract with NAS to conduct reviews of the scientific and medical literature on long-term health effects from exposure to environmental hazards associated with the 1991 Gulf War. Those statutes list approximately 33 specific risk factors or categories of risk factors for consideration by NAS in its review process. VA is further directed to determine if a presumption of service connection is warranted for any illness covered in a NAS report, and to publish a notice of that determination, including an explanation of its scientific basis.

I understand that you are interested in the contracts with NAS, including their status, terms, conditions and timelines. NAS has reviewed many Gulf War environmental hazards in a series of four reports conducted under contract to VA. I will briefly summarize this information, and will be happy to provide copies of the contracts and final reports to you.

The initial NAS report, issued in 2000, on Gulf War health issues reviewed health effects of depleted uranium, sarin, pyridostigmine bromide and vaccines. We understand that the NAS committee selected those specific risk factors for its initial review at the suggestion of Gulf War veterans following initial public meetings they arranged.

To evaluate the NAS report, VA established a Task Force whose members included the Under Secretaries for Health and for Benefits, the Office of General Counsel, and the Assistant Secretary for Policy, Planning and Preparedness. Based on the Task Force's review, VA published a notice in the Federal Register and informed

C Congress that the information provided by NAS did not warrant developing any new presumptive service connections.

The second NAS report, issued in 2002, reviewed health effects of insecticides and solvents (for example, cleaning fluids) used in the 1991 Gulf War. In response, VA's Task Force reviewed the report and provided recommendations to the Secretary. The Department is currently finalizing its notice announcing the Secretary's determination regarding the report.

The third NAS report, issued in 2004, reviewed health effects from fuels (for example, gasoline), combustion products (for example, smog), and propellants (for example, rocket fuels). VA's Task Force reviewed the report and provided recommendations to the Secretary.

E The NAS reports released to date have addressed a wide array of potential exposures presenting different concerns. For example, the reports issued in 2002 and 2004 considered a number of environmental hazards that are generally well-studied and not uncommon workplace or urban exposures, such as gasoline, smog, common pesticides and cleaning solvents. They are known to cause specific illnesses, particularly among civilian workers who may have had very large exposures lasting over many years.

A few environmental hazards associated with the first Gulf War are more unusual—for example, the chemical warfare agent sarin and depleted uranium, both of which were addressed in the 2000 NAS report. Fortunately, IOM had a large amount of medical and scientific literature to review on health effects from exposure to these agents, including animal studies. Thus, in its initial 2000 review and in a follow-up review in 2004, NAS did not identify any illness or disabilities for individuals exposed to trace levels of sarin or that may have occurred during the 1991 Gulf War.

VA's task in reviewing these reports is merely to decide whether additional presumptions of service connection are warranted by current scientific evidence for particular diseases. This process would not in any way limit the right of any veteran under existing claim procedures to establish service connection on a direct basis, and with VA's assistance, for any disease that could be related to their service in the 1991 Gulf War.

Current "Gulf War and Health" Studies

As part of its ongoing legislatively mandated review of Gulf War veterans' health issues, IOM is currently conducting three relevant studies:

- Infectious diseases associated with the Gulf War and Southwest Asia;
- Health effects from deployment-related stress (including veterans involved in the current conflict in Iraq who are technically also Gulf War veterans); and,
- New clinical approaches to treating Gulf War veterans suggested by a complete review of all scientific publications on Gulf War veterans' health.

As with all of the IOM "Gulf War and Health" literature reviews, the specific risk factors examined were selected by IOM, with approval by VA. IOM selects topics based on its analyses of the relevant health and scientific data issues, and of the availability of published literature for review. VA reviews the proposed areas of study only from the standpoint that they must be consistent with IOM's mandate to review Gulf War veterans' health issues as defined in the two relevant statutes. These three studies will be completed and IOM plans to provide them to VA during the current fiscal year.

In addition, VA agreed to contract for an IOM study on peer-reviewed published scientific research on Gulf War veterans as part of studies required by Public Laws 105-277 and 105-368, to look for possible improved medical treatments. The contract was approved May 11, 2004, and is estimated to be completed in December, 2005. The new IOM committee conducting a literature review to assess therapeutic options was formed following a recommendation from IOM to pursue a more comprehensive

evaluation of this issue and make clinical recommendations. This action falls within the IOM's mandate and is routine for IOM.

New IOM committees are formed as part of a long series of committees evaluating potential Gulf War health threats. According to the Gulf War Veterans Act, "Under the agreement . . . the National Academy of Sciences shall separately review, for each chronic undiagnosed illness identified . . . and for any other chronic illness that the Academy determines to warrant such review, the available scientific data in order to identify empirically valid models of treatment for such illnesses which employ successful treatment modalities for populations with similar symptoms." And, "Under the agreement . . . the National Academy of Sciences shall make any recommendations that it considers appropriate for additional scientific studies (including studies relating to treatment models) to resolve areas of continuing scientific uncertainty relating to the health consequences of exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service."

Finally, psychological stress is being evaluated in part because it is seen as a major concern in the current Iraqi conflict, which is taking place in the same geographic area as the Gulf War. The committees conducting the three ongoing IOM studies will assess the health threats for troops serving in Iraq today, who share many hazardous exposures with prior Gulf War veterans. Psychological stress was added to the mix of potential health threats for IOM evaluation because it may be a major co-factor with other environmental health threats. For example, it is hypothesized that greater concentrations of anti-chemical warfare agent, PB, enter the brain during times of stress.

Future Studies

VA recently requested a study from IOM looking at evidence for increased risk of Lou Gehrig's disease among all U.S. veterans, not just Gulf War veterans. This study arose out of concerns raised by a series of recent scientific publications that suggest

that veterans from all eras may be at a greater risk for this disease. It will take an estimated 9 months to complete and was begun in August 2005.

Contractual Relationship Between VA and NAS

I would like to address the contractual relationship between VA and NAS, and the role of NAS in VA's decision-making process that translates its "Gulf War and Health" reports into health care and disability compensation policies. In a June 20, 2005, letter, this Subcommittee requested information on any correspondence from 1997 to 2004 between VA employees and any representatives of IOM regarding studies on Gulf War illnesses and related issues. VA provided its correspondence with representatives of IOM. This information primarily consisted of the basic contracts VA had established with IOM to conduct its periodic reviews of the medical and scientific literature on Gulf War risk factors, as spelled out in the two relevant statutes.

It is important to emphasize that after IOM completes one of its reviews, it is not involved in the Department's decision-making process. As I have noted, following receipt of each IOM report, VA establishes an internal Task Force to consider the report's policy implications. The Task Force in turn prepares recommendations for the Secretary to consider for VA's response.

Part of the value of IOM to both VA and veterans is its reputation for independence and scientific rigor. In support of this, VA does not provide precise guidance to IOM on how to conduct their studies beyond a basic required contract which explicitly states the goal of the study. For information on how IOM incorporates the data from the animal studies it reviews, VA defers to IOM since it can best answer these questions.

Human and Animal Studies Used in Establishing Veteran Disability Compensation Policy

From the outset, VA asks IOM to evaluate all available medical and scientific literature, which includes studies of both humans and animals. The ultimate point of this

process is to evaluate potential human health effects relevant to veterans. Consequently, for all health studies, including those related to the Gulf War, Vietnam veterans, veterans exposed to chemical agents such as mustard agent, and SHAD veterans, VA and IOM emphasize findings from human clinical and epidemiological studies as being the most relevant to the health effects we must anticipate among veterans. Part of this distinction occurs because laboratory animals often do not respond to hazardous exposures in the same manner as humans and, therefore, it can be dangerous to predict clinical effects in humans based solely upon toxicological observations of laboratory animals. For example, in one report IOM described a nearly 40-fold range in toxicity of sarin among various laboratory animals. It is difficult to say which, if any, of these results based upon animal studies would be the most reliable predictor of human toxicity.

Animal studies are essential for planning relevant research studies. But the most useful data for predicting health effects in humans is based upon human studies. In the absence of human studies, animal studies may become the logical starting point for considering potential human health effects. However, when there are numerous human studies available, they will likely be the most reliable predictors of future health effects among humans. Finally, in cases where an effect is observed in an animal study but not observed in a well conducted epidemiological study, then the conclusion would have to be that the animal study is probably not clinically relevant to humans. Approaches that emphasize human studies are consistent with all other biomedical research and the evaluation of clinical effects of drugs and other chemicals because human studies are more reliable than animal studies.

Nevertheless, it would be erroneous to conclude that either IOM or VA somehow excludes data from animal studies from the consideration of possible health effects among humans. For example, in his January 24, 2003, letter to IOM, former Secretary Principi requested an updated study on sarin health effects focused upon new animal studies, and directed IOM to consider the new animal studies:

"Recently, a number of new studies have been published on the effects of Sarin on laboratory animals. These studies have raised concerns with Gulf War veterans and other Americans regarding the relationship of these studies to possible health consequences of human exposures.

With this in mind, I am requesting IOM examine the medical and scientific literature on health effects of Sarin published since the 2000 Report. I ask that IOM report back to VA, as soon as possible, on whether this new research affects earlier conclusions of IOM on Sarin health effects."

On examination of this requested report, it is clear that the IOM committee reviewed numerous animal studies in reaching their conclusions. In chapter two, titled "Toxicology," of the 2004 report, "Gulf War and Health: Updated Literature Review of Sarin," (pages 26 to 46), the IOM committee cites results from 101 animal studies and reviews.

The committee also reviewed many, directly applicable human studies, including studies of Gulf War veterans possibly exposed to Sarin as a result of the demolitions at Khamisiyah, Iraq. The committee reviewed 19 epidemiological studies of sarin health effects. These included three studies of non-Gulf War veterans, four studies of Gulf War veterans potentially exposed at Khamisiyah, six population-based studies of U.S. and U.K. Gulf War veterans using self-reported exposures, and six studies of specific military units of Gulf War veterans also using self-reported exposures. They also reexamined all of the studies used in an earlier IOM report, issued in 2000, on Sarin health effects.

The human studies IOM analyzed were highly relevant to evaluating possible effects among Gulf War veterans. The non-Gulf War veteran studies reviewed were based upon U.S. military volunteers who had been exposed several decades ago to non-lethal doses of sarin and other chemical warfare agents; on industrial workers with

documented acute exposure to sarin; and upon victims of the sarin terrorist attacks in Matsumoto City in 1994 and Tokyo in 1995.

In reviewing published studies, the IOM committee based its determinations on the strength of the evidence of associations between compound exposure and human health effects as reported in those studies. The committee also considered other relevant issues, including exposure to multiple chemicals and genetic susceptibilities. According to its report, the committee's findings represent its collective judgment expressed "as clearly and as precisely as the available data allowed" by using previously established categories of association.

The committee also specifically reviewed the new published data from laboratory animals that had precipitated interest in an updated study of sarin health effects, mentioned by former Secretary Principi in his letter. The committee concluded that the animal studies were an important step in "determining whether a biologically plausible mechanism could underlie any long-term effects of low exposure to chemical nerve agents, but more work needs to be conducted to elucidate potential mechanisms and clarify how the cellular effects are related to any clinical effects that might be seen."

Following publication, the IOM committee provided a briefing to VA on its new report. At the briefing, the issue was raised that the IOM emphasis on human studies might possibly overlook health concerns revealed exclusively in laboratory animal studies. The chair of the IOM committee acknowledged this concern, but stated the committee thoroughly reviewed available animal studies, and concluded that taken together the studies failed to show consistent biological effects that could be plausibly tied to potential clinical effects in humans. He added that future animal studies might change this conclusion.

Finally, as I mentioned earlier, the VA Task Force has the responsibility to evaluate IOM committee reports and to decide if any new presumptive service connections are warranted. VA has wide statutory authority to make such a determination based on all

"sound medical and scientific evidence," and is not limited solely to the IOM committee findings. The VA Task Force places substantial weight upon the independent and authoritative IOM committee's findings, but it also considers other relevant information. VA has responsibility for determining what weight to place upon various studies in reaching any health care or disability compensation policy conclusions. Finally, VA publishes a notice in the Federal Register and informs Congress on these findings. Based upon this approach, VA complies with statutory mandates to assess the extent and weight of data from human and animal studies in developing presumptive service connection policies.

Thank you, again, for the opportunity to be here today. My colleagues and I would be happy to answer any questions that you may have.

Attachment:

Previous Studies Specifically on Gulf War Veterans' Health Conducted by IOM

1. "Gulf War and Health: Volume 3. Fuels, Combustion Products, and Propellants." Committee on Gulf War and Health, Literature Review of Selected Environmental Particulates, Pollutants, and Synthetic Chemical Compounds, Board on Health Promotion and Disease Prevention, Institute Of Medicine of The National Academies, The National Academies Press, Washington, D.C., 516pp, 2005.
2. "Gulf War and Health: Updated Literature Review of Sarin." Committee on Gulf War and Health: Updated Literature Review of Sarin, Board on Health Promotion and Disease Prevention, Institute of Medicine of *The National Academies*, The National Academies Press, Washington, D.C., 132pp, 2004.
3. "Gulf War and Health: Volume 2. Insecticides and Solvents." Committee on Gulf War and Health: Literature Review of Pesticides and Solvents, Board on Health Promotion and Disease Prevention, Institute Of Medicine of The National Academies, The National Academies Press, Washington, D.C., 616pp. 2003.
4. "Gulf War Veterans: Treating Symptoms and Syndromes." Committee on Identifying Effective Treatments for Gulf War Veterans' Health Problems, Board on Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 162pp, 2001.
5. "An Assessment of the Safety of the Anthrax Vaccine: A Letter Report." Committee on Health Effects Associated with Exposures During the Gulf War, Institute of Medicine, Washington, D.C., 13pp, 2000.
6. "Gulf War and Health: Volume 1. Depleted Uranium, Pyridostigmine Bromide, Sarin, and Vaccines." Committee on Health Effects Associated with Exposures During the Gulf War, Division of Health Promotion and Disease Prevention, National Academy Press, Washington, D.C., 432pp, 2000.
7. "Protecting Those Who Serve: Strategies to Protect the Health of Deployed U.S. Forces." Committee on Strategies to Protect the Health of Deployed U.S. Forces Institute of Medicine, National Academy Press, Washington, D.C., 112pp, 2000.
8. "Strategies to Protect the Health of Deployed U.S. Forces: Detecting, Characterizing, and Documenting Exposures." Division of Military Science and Technology, Commission on Engineering and Technical Systems, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, D.C., 272pp, 2000.
9. "Gulf War Veterans: Measuring Health." Committee on Measuring the Health of Gulf War Veterans, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 136pp, 1999.

10. "Strategies to Protect the Health of Deployed U.S. Forces: Medical Surveillance, Record Keeping, and Risk Reduction." Medical Follow Up Agency, Institute of Medicine, National Academy Press, Washington, D.C., 296pp, 1999.
11. "National Center for Military Deployment Health Research." Committee on a National Center on War-Related Illnesses and Postdeployment Health Issues, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 62pp, 1999.
12. "Measuring the Health of Persian Gulf Veterans: Workshop Summary." Committee on Measuring the Health of Persian Gulf Veterans, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 42pp, 1998.
13. "Adequacy of the VA Persian Gulf Registry and Uniform Case Assessment Protocol." Committee on the Evaluation of the Department of Veterans Affairs Uniform Case Assessment Protocol, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 208pp, 1998.
14. "Adequacy of the Comprehensive Clinical Evaluation Program: A Focused Assessment." Committee on the Evaluation of the Department of Defense Comprehensive Clinical Evaluation Program, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 144pp, 1997.
15. "Adequacy of the Comprehensive Clinical Evaluation Program: Nerve Agents." Committee on the Evaluation of the Department of Defense Comprehensive Clinical Evaluation Program, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, D.C., 64pp, 1997.
16. "Health Consequences of Service During the Persian Gulf War: Recommendations for Research and Information Systems." Committee to Review the Health Consequences of Service During the Persian Gulf War, Medical Follow Up Agency, Institute of Medicine, National Academy Press, Washington, DC, 26pp, 1996.
17. "Health Consequences of Service During the Persian Gulf War: Initial Findings and Recommendations for Immediate Action." Committee to Review the Health Consequences of Service During the Persian Gulf War, Medical Follow Up Agency, Institute of Medicine, National Academy Press, Washington, DC, 104pp, 1995.
18. "Evaluation of the US Department of Defense Persian Gulf Comprehensive Clinical Evaluation Program." Committee on the DoD Persian Gulf Syndrome Comprehensive Clinical Evaluation Program, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy Press, Washington, DC, 57pp, 1995.